

**510(k) Summary of Safety and Effectiveness**

**OCT 31 2012**

**SAFE MEDICAL DEVICES ACT OF 1990**

**510(k) Summary**

**NAME OF FIRM:** BioPro, Inc.  
2929 Lapeer Road  
Port Huron, MI 48060

**510(k) FIRM CONTACT:** Al Lippincott  
Engineering Consulting Services, Inc.  
3150 E. 200<sup>th</sup> St.  
Prior Lake, MN 55372  
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**DATE:** June 22, 2012

**TRADE NAME:** **BioPro Hemi-Edge Toe System**

**COMMON NAME:** Prosthesis, Toe, Hemi, Phalangeal

**CLASSIFICATION:** Toe joint phalangeal (hemi-toe) prosthesis (21CFR, Sec. 888.3730)

**DEVICE PRODUCT CODE:** **KWD**

**SUBSTANTIALLY  
EQUIVALENT DEVICES** BioPro Hemi MP Joint (K041595)  
Townley Great Toe Joint (K911378)

**DEVICE DESCRIPTION:** The BioPro Hemi-Edge Toe System will be available in two material options: it can be manufactured from either Cobalt Chrome (ASTM F1537) or Titanium 6-4 (ASTM F1472). The system will be available in 5 sizes in both porous and non-porous coated versions as a press fit design. The basic implant design is unchanged to the original design which consists of a contoured articulating surface to simulate the normal concave articulation of the proximal phalanx in the toe.<sup>1,2</sup> The current implant is a modification to the original implant design which includes a partial surrounding lip or rim adjacent the outer perimeter of the articulating surface. The purpose of the lip/rim is to prevent osteophyte bone on-growth to the articular surface that could inhibit function of the device. Two(2) small windows in opposite corners of the lip/rim allow either visual or needle verification in seating of the prosthesis on resected bone. The current implant design still includes the diamond shaped stem which provides a press-fit intra-medullary fixation. Ancillary instrumentation is available for device implantation and removal. The implant is sold in a 'sterile' condition for single-use. The sterilization method used is Ethylene Oxide.

**INTENDED USE:**

- i. A press fit implant for arthritic degradation of the metatarso-phalangeal joint that has resulted in disabling pain, limited motion and loss of the normal ambulatory function of the forefoot.
- ii. Degenerative arthritis
- iii. Rheumatoid arthritis
- iv. Bunion deformity associated with arthritis of the metatarsal-phalangeal joint
- v. A titanium version is available for use only in patients susceptible to nickel-chromium allergies.

The BioPro Hemi-Edge Toe System is not intended for spinal use.

**EQUIVALENCE:**

The BioPro Hemi-Edge Toe System is Substantially Equivalent(SE) to the predicate systems. No nonclinical testing was used in the determination of substantial equivalence.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The BioPro Hemi-Edge Toe System is Similar in Material, Geometry Design/Markings, and Indications to the predicate system(s) currently sold in the U.S. market.

**SUMMARY OF SAFETY AND EFFECTIVENESS:**

The BioPro Hemi-Edge Toe System is shown to be safe and effective for use as 'sterile' and for single-use in a surgical setting.

**Cited References:**

1. Giza E, Sullivan MR. First Metatarsophalangeal Hemiarthroplasty for Grade III and IV Hallux Rigidus. *Techniques in Foot and Ankle Surgery*. 4(1):10-17, 2005.
2. Townley CO, Taranow WS. A Metallic Hemiarthroplasty Resurfacing Prosthesis for the Hallux Metatarsophalangeal Joint. *Foot & Ankle International*. 1994;15(11):575-80.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

BioPro, Incorporated  
% Engineering Consulting Services, Incorporated  
Mr. Al Lippincott  
Medical Engineer and Consultant  
3150 East 200<sup>th</sup> Street  
Prior Lake, Minnesota 55372

OCT 31 2012

Re: K121973

Trade/Device Name: BioPro Hemi-Edge Toe System  
Regulation Number: 21 CFR 888.3730  
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis  
Regulatory Class: Class II  
Product Code: KWD  
Dated: October 10, 2012  
Received: October 18, 2012

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

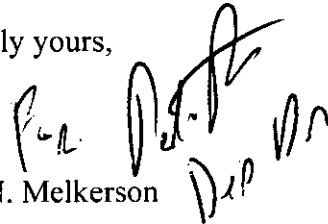
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) NUMBER: K121973

DEVICE NAME: BioPro Hemi-Edge Toe System

- a. A press fit implant for arthritic degradation of the metatarso-phalangeal joint that has resulted in disabling pain, limited motion and loss of the normal ambulatory function of the forefoot.
- b. Degenerative arthritis
- c. Rheumetoid arthritis
- d. Bunion deformity associated with arthritis of the metatarsal-phalangeal joint
- e. A titanium version is available for use only in patients susceptible to nickel chromium allergies.

The BioPro Hemi-Edge Toe System is not intended for spinal use.

Prescription Use XXXXXXXXXX AND/OR Over-The-Counter-Use \_\_\_\_\_

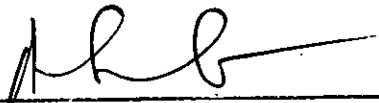
(Per 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K121973